

REMARKS

The Office Action dated June 10, 2003 presents the examination of claims 1-9 and 11-17. No amendments are made and no new matter is inserted into the application.

Rejection under 35 U.S.C. § 103(a)

The Examiner maintains the rejection of claims 1, 3-9, 11, and 13-17 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Bradfield '283 (U.S. Patent 5,650,283), in view of Waldman et al. (*Analytical Biochemistry* 258:216-222(1998)).

The Examiner maintains the rejection of claims 2 and 12 under 35 U.S.C. § 103(a) for allegedly being unpatentable over Bradfield '283, in view of Waldman et al., and further in view of Kushner '638 (U.S. Patent 6,117,638).

Applicants respectfully traverse the rejections. Reconsideration of the claims and withdrawal of the instant rejections are respectfully requested.

The present invention provides an animal cell expressing a gene coding a ligand-responsive transcription control factor and securely maintaining a DNA comprising in a molecule, a reporter gene (a) connected downstream from a transcription control

region which substantially consists of a recognition sequence of the ligand-responsive transcription control factor and a minimum promoter, and a selective marker gene (b); but does not contain a reporter gene (c). In such a cell, the constitutive background transcription activity (which hinders the measurement of transcription activity) is lowered, such that the detection of ligand-responsive transcription activity can be conducted with higher sensitivity (see page 20, lines 11 to 13; and Example 4 of the specification). In Example 4, transformed cells (i.e., the cells of the present invention) obtained by introducing DNA of ① pGL3-TATA-EREx5-BSD (containing "TATA DNA") and pRC/RSV-hER α Kozak provided clones having a high ratio (i.e., not less than 50-fold) of luciferase activity in a system containing 17 β estradiol (i.e., ligand-responsive transcription activity) to luciferase activity in a system containing no added 17 β estradiol (i.e., constitutive background transcription activity). On the contrary, transformed cells obtained by introducing DNA of ② pGL3-tk-EREx5-BSD (containing the HSV-tk promoter region, which comprises a recognition sequence of the other transcription control factor in addition to a minimum promoter, instead of "TATA DNA") and pRC/RSV-hER α Kozak failed to provide clones having a high ratio (for example, not less

than 50-fold) of luciferase activity in a system containing 17β estradiol to luciferase activity in a system containing no added 17β estradiol. Thus, the present invention provides an animal cell wherein ligand-responsive transcription activity can be measured with a high specificity even in the presence of constitutive background transcription activity.

None of the references cited (Bradfield '283, Waldman et al., and Kushner '638) teach or suggest to the ordinary skilled artisan that an animal cell securely maintaining a DNA comprising in a molecule, a reporter gene (a) connected downstream from a transcription control region which substantially consists of a recognition sequence of the ligand-responsive transcription control factor and a minimum promoter, and a selective marker gene (b), would show higher sensitivity in detection of ligand-responsive transcription activity. Accordingly, the skilled artisan would not have been motivated to combine the teachings of the references cited in order to obtain stably transformed animal cells in which ligand-responsive transcription activity can be detected with higher sensitivity.

For the above reasons, Applicants respectfully submit that the cited combinations of Bradfield '283 in view of Waldman et

al. and Bradfield '283 in view of Waldman et al. and Kushner '638 fail to render the present invention obvious. Withdrawal of the instant rejections is respectfully requested.

Conclusion

Applicants respectfully submit that the above remarks fully address and overcome the outstanding rejections and objections. For the foregoing reasons, Applicants respectfully request the Examiner to withdraw all of the outstanding rejections, and to issue a notice of allowance indicating the patentability of the present claims. Early and favorable action of the merits of the present application is thereby respectfully requested.

If there are any minor matters precluding allowance of the application which may be resolved by a telephone discussion, the Examiner is respectfully requested to contact Kristi L. Rupert, Ph.D. (Reg. No. 45,702) at (703) 205-8000.

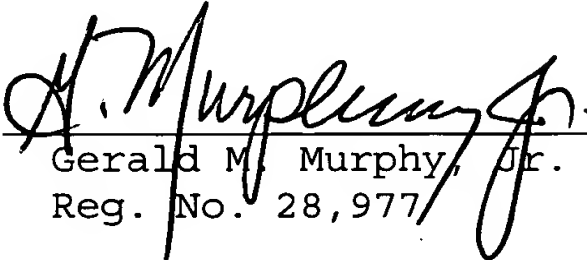
If necessary, the Commissioner is hereby authorized in this, concurrent, and further replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any

Application No. 09/550,173


additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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